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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,559	07/24/2003	Ludwig Zorn	SCH-1915	8097
23599	7590	09/29/2006	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			HANLEY, SUSAN MARIE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,559

Applicant(s)

ZORN ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 11-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-10, and the microorganism species *Glomerella sp.* in the reply filed on 5/30/06 is acknowledged. The traversal is on the ground(s) that a search of all the claims would comprise overlapping subject matter and that there is no undue burden on the examiner to search all of the claims. This is not found persuasive because it was shown in the restriction requirement that the groups have separate classification and that the compounds can be made by purely chemical methods. Regarding Applicant's argument that the search for both inventions is not a serious burden on the Examiner, it is noted that a comprehensive search, as required by the Office, is not merely limited to the patent documents found in the class and subclass of the invention's classification. A review of extensive and multitudinous records in the various and appropriate commercial databases is also required and places a serious burden on the examiner if forced to search and examine both inventions. Furthermore, the scope of the compounds embraced by the product claims is much wider than that of the process claims. It is also noted that the search is not merely limited to narrow aspects of the prior art, but also is necessary for the Examiner to make appropriate determinations as to the enablement and clarity of the claims in view of the specification. Thus, the restriction between the two inventions is clearly proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/30/06.

***Specification***

The title of the invention is objected to because it is too long. According to the MPEP section 606, the title of the invention may not exceed 500 characters in length and must be as short and specific as

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possible. Characters that cannot be captured and recorded in the Office's automated information systems may not be reflected in the Office's records in such systems or in documents created by the Office.

#### *Claim Suggestions*

In claims 1, 3 and 6 it is suggested that the phrase "with general formula" be changed to "having the formula" or "having the structure" for ease of reading.

In claim 1, 3 and 6, it is suggested.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The claims recite the limitation "use of a microorganism." The word "use" does not set forth any positive process steps regarding how the reactants and microorganisms are brought together to obtain the desired product.

Claims 1-8 are rejected because they recite the phrase "a microorganism that is selected from the group that comprises...". It is unclear if this phrase is intended to recite a Markush group. The recitation of a proper Markush group has the wording "that is selected from the group consisting of."

Claim 8 recites the limitation "wherein R<sub>13</sub> stands for CH<sub>3</sub>". There is insufficient antecedent basis for this limitation in any one of the preceding claims because R<sub>7</sub> is the grouping P-Q, wherein P is an alkylene group and Q is an alkyl or fluoroalkyl group that is bonded to the steroid skeleton through P. This limitation requires that P is always present. Thus, the minimum P-Q grouping is an alkylene group

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bonded to an alkyl or fluoroalkyl group. The methyl group of claim 8 corresponds to Q, but the claim lacks the P (alkylene) moiety.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6, 8, 9 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Babcock et al. (US 3,341,557; "Babcock").

Babcock discloses that the steroid having formula X shown in Reaction Scheme B can be hydroxylated at the 11-position to provide the compound XI. Compound X corresponds to compound D in claim 6, wherein  $R_7 = \text{Me}$  (as in instant claim 8),  $R_{10} = \text{H}$  (as in instant claim 9) and  $R_{13} = \text{Me}$  (as in instant claim 10). The selective hydroxylation is carried out by incubating the compound X with a microbe capable of alpha-hydroxylating the 11-position. Some of these microbes are from the genera *Penicillium*, *Aspergillus*, etc. (col. 10, lines 1-15 and 36-41). This disclosure anticipates the generic claim 6.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

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owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babcock et al. (US 3,341,557; "Babcock") in view of Carvajal et al. (US 2,985,563).

The disclosure by Babcock is discussed supra.

Babcock does not teach that the hydroxylation is carried out by a microbe belonging to the elected species *Glomerella* sp.

Carvajal discloses that any number of specie from the genus *Glomerella* can catalyze the alpha-hydroxylation of the 11-position of the steroid ring (col. 3, lines 13-14) and col. 1, lines 51-70).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the alpha-hydroxylation of compound X taught by Babcock with a fungus from the genera *Glomerella*. The ordinary artisan would have been motivated to do so because the microbes taught by Babcock and Carvajal are functional equivalents in that they catalyzes the same hydroxylation reaction with the same stereoselectivity to the 11-position of the steroid ring. Thus, the selection of a suitable microbe to accomplish the desired transformation would have been a routine matter of selection of a known equivalent hydroxylating agent (microbe). The ordinary artisan would have had a reasonable expectation that the *Glomerella* sp. would be able to accomplished the hydroxylation reaction because Carvajal demonstrated that said microbe could reliably carry out the reaction with a variety of steroids.

No claim is allowed.

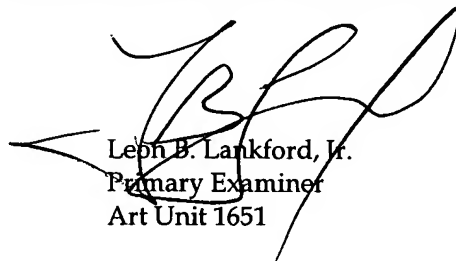
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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